510(k) Summary Pursuant to 21 CFR 807.92

Sponsor: Pioneer Surgical Technology, Inc.
375 River Park Circle
Marquette, MI 49855 USA
Ph: (906) 225-5602
Fx: (906) 226-4459

Contact: Emily Downs
Prepared: June 28, 2013

Trade name: NB3D (nanOss Bioactive 3D) Bone Void Filler
Common name: Bone Void Filler

Classification: 21 CFR 880.3045 Filler, Bone Void, Calcium Compound; Class II

Product Code: MQV

Panel/ Branch: Orthopaedic and Rehabilitation Devices Panel; Panel Code 87
Restorative Devices Branch

Predicates: K111944 NB3D Bone Void Filler (SE 11-22-2011)
K083033 Vitoss Bone Graft Substitute, Vitoss Bone Graft Substitute filled Canister, Vitoss Foam Bone Graft Substitute, Vitoss Bioactive Foam Bone Graft Substitute (SE 11-6-2008)

Description: NB3D is a resorbable porous, calcium phosphate bone void filler that provides a scaffold for the in-growth of new bone. NB3D is an osteoconductive implant with an interconnected porosity similar to human cancellous bone.

NB3D is a semi-rigid three dimensional construct that consists of porous hydroxyapatite granules suspended within porous porcine gelatin-based foam matrix. It is provided in the form of strips and shapes that can be further cut as required at the time of surgery.

When hydrated at the point of use, NB3D becomes a compressible and elastic sponge that allows the shape of the implant to conform to the defect maximizing direct contact with viable host bone. nanOss Bioactive 3D is provided sterile by prior exposure. NB3D is provided with a sterile, single use syringe.

This 510(k) expended clearance of NB3D for use in bony voids or gaps of the skeletal system (extremities and pelvis) and added various shapes.

Intended Use:	NB3D is indicated for bony voids or gaps that are not intrinsic to the stability of the bony structures. These defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone. NB3D is indicated to be gently packed into bony voids or gaps of the skeletal system (extremities and pelvis) un-hydrated or in conjunction with bone marrow aspirate or autogenous blood, or in the posterolateral spine in conjunction with bone marrow aspirate and autograft bone as a bone graft extender. The product provides a bone void filler that resorbs and is replaced with bone during the healing process.
Substantial Equivalence	This submission supports the position that the subject system is substantially equivalent to previously cleared bone void fillers based on comparison of indications for use, intended use, materials, technological characteristics, and animal testing. Pioneer Surgical Technology submits the following information in this Premarket Notification to demonstrate that, for the purposes of FDA's regulation of medical devices, NB3D is substantially equivalent in indications and design principles to the above predicate devices, each of which has been determined by FDA to be substantially equivalent to pre-amendment devices. The subject device and the predicate devices are bone void fillers that are intended for bony voids or gaps that are not intrinsic to the stability of the bony structure.
Pre-Clinical Performance Data:	Animal testing performed to demonstrate substantial equivalence included determination radiographic appearance, histomorphometric properties, and histological response of the subject device and the predicate K083033 Vitoss Foam Strip when implanted in a rabbit critically sized defect model. This testing demonstrated that the device is as safe, as effective and performs as well as or better than the predicate device and comparable to autograft.
Technological Characteristics:	The Technological Characteristics of NB3D are identical to that of predicate K111944, and similar to predicate K083033 to such an extent that no new questions of Safety and Effectiveness are raised. A summary of those similarities is provided in the Table below:

Comparison Feature	Subject NB3D (nanOss Bioactive 3D) Bone Void Filler
Indication for Use	PL Spine, pelvis, extremities Same as K083033. Extension to K111944.
Operating Principle	Same as K111944 and K083033
Basic Design	Same as K111944
Form	Same as K111944
Performance	Performed SE to K083033
Manufacturing Principles	Same as K111944
Sterilization	Same as K111944
Shelf-Life	Same as K111944
Packaging	Same as K111944
Material Composition	Same as K111944
Use of Rigid Fixation	Same as K111944 and K083033
S & E Profile	Same as K111944 and K083033
Volume, cc	1-52cc; Same as K111944
Shapes/sizes	Strips, Shapes and Cylinders Dimensionally similar to K111944 and K083033

The fundamental scientific technology of the subject system, device characteristics, components, material composition and design are the same as the predicate devices. There are no significant differences between NB3D Bone Void Filler and the predicate devices which would adversely affect the use of the product.

Conclusion:

The subject system is substantially equivalent to valid predicate devices and in this submission was found to be at least as safe and effective as the predicate device based on similarities in materials, technology, labeling and performance.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

February 7, 2014

Pioneer Surgical Technology, Incorporated
Ms. Emily Downs
Director, Regulatory and Clinical Affairs
375 River Park Circle
Marquette, Michigan 49855

Re: K132050
Trade/Device Name: NB3D Bone Void Filler
Regulation Number: 21 CFR 888.3045
Regulation Name: Resorbable calcium salt bone void filler device
Regulatory Class: Class II
Product Code: MQV
Dated: December 19, 2013
Received: December 26, 2013

Dear Ms. Downs:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Vincent J. Devlin -S

for
Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number: K132050

Device Name: NB3D Bone Void Filler:

Indications for Use:

NB3D is indicated for bony voids or gaps that are not intrinsic to the stability of the bony structures. These defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone. NB3D is indicated to be gently packed into bony voids or gaps of the skeletal system (extremities and pelvis) un-hydrated or in conjunction with bone marrow aspirate or autogenous blood, or in the posterolateral spine in conjunction with bone marrow aspirate and autograft bone as a bone graft extender. The product provides a bone void filler that resorbs and is replaced with bone during the healing process.

Prescription Use			Over-The-Counter Use
(Part 21 CFR 801 Subpart D)	X	AND/OR	(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Laurence D. Coyne -S

(Division Sign-Off)
Division of Orthopedic Devices
510(k) Number: K132050